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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, WESTERN DIVISION

HUMANA INC.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and MALLINCKRODT PLC,

Defendants.

Case No. 2:19-cv-06926

DEMAND FOR JURY TRIAL

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COMPLAINT

Plaintiff Humana Inc. ("Plaintiff" or "Humana"), complains against Defendants Mallinckrodt ARD LLC, formerly known as Questcor Pharmaceuticals, Inc. ("Questcor"), and its parent corporation Mallinckrodt plc (collectively "Defendants," "Mallinckrodt," or the "Company"), as follows:

I. INTRODUCTION

1. This action arises from one of the most outrageous price-gouging schemes in the history of American medicine.

2. H.P. Acthar Gel ("Acthar") is a drug that has been available since 1952, and for nearly half a century, its price was modest. In 2001, a vial of the drug cost $40.

3. But by 2018, the same vial cost over $39,000. This is a 97,500% price increase. It is as if the price of milk increased from $3 to over $2,900 per gallon, or a mortgage payment rose from $2,000 to over $2 million per month.

4. These eye-popping price increases are not an accident, a market anomaly, or a necessary byproduct of legislation. They are the intended result of purposeful and illegal conduct by Acthar's producers, Mallinckrodt and its predecessor Questcor. This conduct consists of a complex, multipart scheme involving monopoly, bribery, racketeering, fraud, and other deceptive and unfair practices that have imposed exorbitant and pointless costs on those financially responsible for the costs of the drug, including not just patients but also health and Medicare insurers like Humana, the plaintiff here.

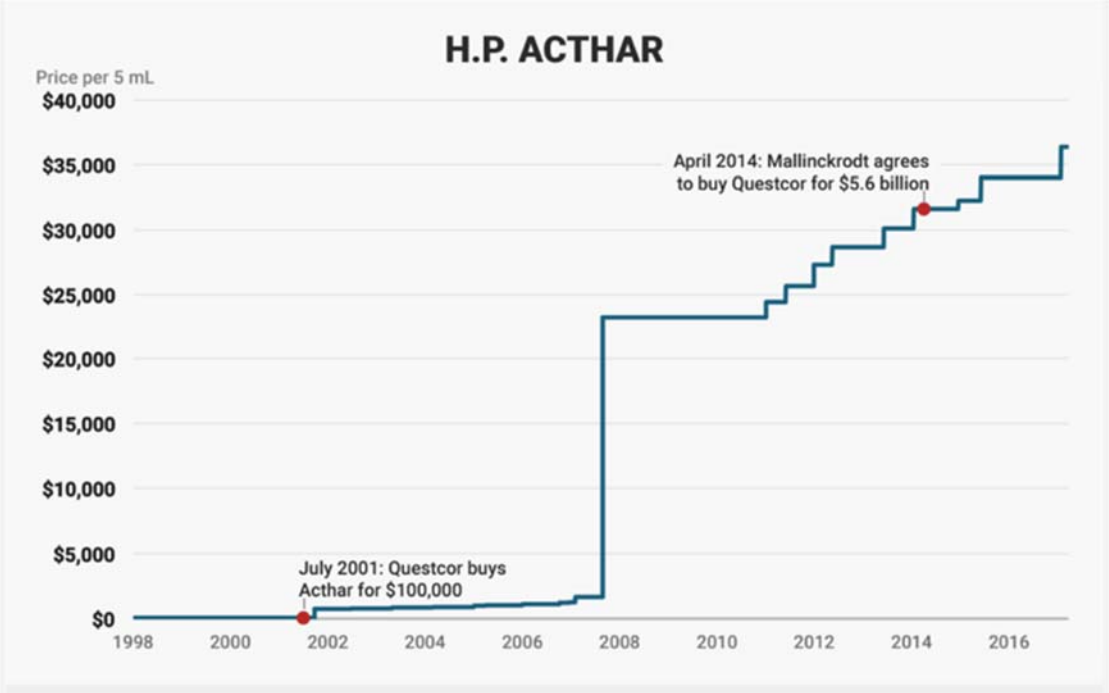
5. Though Acthar may be a billion-dollar golden goose for Mallinckrodt today, its origins were humble. The drug is an adrenocorticotropic hormone ("ACTH") analogue produced from the pituitary gland of pigs. It was invented in the late 1940s by the meat company Armour, as a byproduct of pork-processing operations. At the time, Acthar was considered a miracle drug because it stimulated the body's production of cortisol, provoking a natural anti-inflammatory response that was beneficial for the treatment of various conditions. Acthar was given broad approval by the FDA in 1952

to treat a wide range of ailments at a time when such broad approvals were commonplace and did not require support from clinical trials.

6. This also occurred before the commercial development of synthetic steroid drugs (corticosteroids) and many popular non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen. The advent of these safe, cheap alternative treatments in pill form reduced the need for an injectable drug derived from the pituitary gland of pigs. By the 1990s, only a few key uses remained for Acthar. For example, Acthar remains the standard of care for infantile spasms, a rare but catastrophic epileptic syndrome affecting babies and toddlers two years old or younger. But other than this and a handful of similarly rare conditions, Acthar is—especially for older patients who are Medicare beneficiaries, such as Humana members—either a drug of last resort or not known to be clinically effective.

7. Consequently, the drug became unprofitable for its manufacturer, Aventis Pharmaceuticals, Inc., which had considered stopping production. But the drug was saved in 2001, when Mallinckrodt's predecessor Questcor purchased the right to produce this unprofitable and largely outdated drug for $100,000 plus modest royalties, seeing it as a potential gold mine for exploitation.

8. Thereafter began a run of outrageous price increases. The cost of Acthar ballooned from $40 in 2001, to $750 immediately after it was acquired, to $1,650 by 2007. In that year the price was jacked up to $23,269 per vial. But the increases did not stop or reverse course: instead the price of Acthar was increased eight more times so that by 2018, the drug cost $38,892 per vial. And since treatment with Acthar usually requires at least three vials, a single course of treatment can cost nearly $120,000. The following charts the course of Acthar pricing:



9. In just over a decade, Acthar went from a nearly extinct, financial sinkhole to a billion-dollar cash machine. In August 2014—in the midst of this meteoric price rise—Questcor merged into Mallinckrodt in a deal worth approximately $5.6 billion. At the time, Acthar was the only drug product sold by Questcor.

10. Mallinckrodt has been able to inflate and maintain the shocking price increases of Acthar mainly through three types of improper conduct.

11. *First*, Mallinckrodt eliminated the competition. It did so by acquiring and then shelving the rights to Acthar's much cheaper synthetic equivalent ACTH, a drug called Synacthen Depot ("Synacthen"). Drug giant Novartis AG ("Novartis") was already selling Synacthen in Europe, Asia, and Latin America, but the drug was not approved for use in the United States. After Novartis launched an auction for Synacthen, Mallinckrodt substantially outbid the competition for the rights to Synacthen in the U.S. But rather than undertake the process of obtaining FDA approval for the only drug that was a direct competitor of its best-selling product, Mallinckrodt never seriously attempted to bring Synacthen to market for any clinical use for which Acthar was approved. This kept the price of Acthar artificially high. In addition, Mallinckrodt vertically integrated its sales by distributing Acthar exclusively through

the specialty pharmacy CuraScript. CuraScript had no role in decisions on Acthar's pricing. Because of Mallinckrodt's anticompetitive behavior, the FTC and several states sued it for antitrust violations and later reached a $100 million settlement, as well as an agreement that Mallinckrodt would sublicense its Synacthen rights to a third party.

12. *Second*, Mallinckrodt increased and then maintained artificially high demand for Acthar by using a charitable foundation for the illegal purpose of paying patient co-pays. This fund—initially called the Chronic Disease Fund, now doing business as Good Days—provided "patient assistance" funds for Acthar only, and not for other drugs. Mallinckrodt financed the foundation, directed patients to the fund, paid their co-pays as "donations," and then marketed the drug as "free." In other words, it was a bribe to patients and a vehicle through which Mallinckrodt could persuade physicians that the astronomical price of the drug should not be a barrier to prescribing it. It also constituted a fraud on Medicare, which is why the Department of Justice recently brought claims against Mallinckrodt under two federal statutes, the False Claims Act, 31 U.S.C. §§ 3729-3733, and the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). In addition, this conduct constituted a fraud on Humana (one of the nation's largest sponsors of Medicare Advantage plans) and an intentional interference in Humana's relationship with its insureds, because it removed the incentive for patients to exercise the responsibility ordinarily imposed by co-pays, deductible limits, and other out-of-pocket costs set forth in Humana's agreements with its insureds.

13. *Third*, Defendants simultaneously maintained this artificially high demand through a pervasive bribery scheme to doctors. It should go without saying that doctors would not otherwise be inclined to prescribe what for most purposes is an antiquated and expensive drug that requires refrigeration and injection when cheaper, more effective pills and remedies were available. Furthermore, though Acthar is a first-line treatment for infantile spasms, that market is small and Mallinckrodt sought to redirect its marketing efforts away from the poor public-relations consequences of earning billions of dollars off the backs of sick children. Consequently, Mallinckrodt

aggressively marketed the drug for the treatment of conditions more common among adult patients, including those eligible for Medicare. So under the guise of "education" and "marketing," Mallinckrodt paid millions of dollars to thousands of doctors to encourage the use of Acthar even for conditions where it is not the first-line treatment. Though payment of modest expenses to doctors by pharmaceutical companies may frequently be lawful and harmless, here Mallinckrodt crossed well over the line by paying thinly disguised bribes to at least 20 doctors—mainly rheumatologists, neurologists, and nephrologists—responsible for a significant number of prescriptions. Mallinckrodt paid this group of physicians at least $250,000 each over a three-year period. Not surprisingly, physicians who received more than $10,000 from Mallinckrodt prescribed more than double the amount of Acthar as those who received $25 or less. Also not surprising: fewer than 10% of Acthar prescriptions are now for treatment of infantile spasms.

14. Humana, a Medicare Part D provider, has paid more than $700 million over more than eight years for Acthar. It paid an inflated price due to Mallinckrodt's monopolization and racketeering, and reimbursed unnecessary Acthar treatments due to the prescribing doctors' misrepresentations that they had not received any illegal kickbacks. By this action, Humana seeks to recoup from Mallinckrodt its ill-gotten gains.

II. PARTIES

15. **Humana.** Plaintiff Humana Inc. ("Humana") is a Delaware corporation with its principal place of business at 500 West Main Street, Louisville, Kentucky. Humana and its subsidiaries are providers of healthcare related services, including insuring risk for prescription drug costs for more than eight million members in all 50 states, the District of Columbia, and Puerto Rico. More than 75% of Humana's total premium revenues in the year 2012 were derived from contracts with the federal government, including Medicare Part D prescription drug coverage and Medicare Advantage plans. Humana operates its insurance businesses through a variety of wholly

owned subsidiaries, all of which have assigned their relevant claims in this action to Humana.[1]

16. **Mallinckrodt.** Defendant Mallinckrodt ARD LLC has its principal place of business at 1425 Route 206, Bedminster, NJ, 07921. Mallinckrodt ARD LLC was previously named Mallinckrodt ARD, Inc., and before that was named Questcor Pharmaceuticals, Inc.

17. Mallinckrodt ARD LLC is a subsidiary of defendant Mallinckrodt plc, an Irish public limited company. On April 4, 2014, Mallinckrodt plc entered into an Agreement and Plan of Merger with Questcor and absorbed Questcor as a wholly owned subsidiary on August 14, 2014 for approximately $5.6 billion. At all times relevant to this action, Mallinckrodt plc was an active participant in the schemes of its subsidiary, acting with knowledge of its subsidiary's conduct. Indeed, it was the then-existing and proposed conduct of Questcor that caused Mallinckrodt to acquire Questcor in the first place.

[1] Some of the subsidiaries through which Humana conducts insurance business include: Arcadian Health Plan, Inc., CarePlus Health Plans, Inc., Cariten Health Plan, Inc., Cariten Insurance Company, CHA HMO, Inc., CompBenefits Insurance Company, Emphesys Insurance Company, Health Value Management, Inc. d/b/a ChoiceCare Network, Humana Behavioral Health, Inc., HumanaDental, Inc., Humana Benefit Plan of Illinois, Inc., Humana Employers Health Plan of Georgia, Inc., Humana Health Benefit Plan of Louisiana, Inc., Humana Health Company of New York, Inc., Humana Health Insurance Company of Florida, Inc., Humana Health Plan of California, Inc., Humana Health Plan of Ohio, Inc., Humana Health Plan of Texas, Inc., Humana Health Plan, Inc., Humana Health Plans of Puerto Rico, Inc., Humana Health Plan of Ohio, Inc., Humana Insurance Company, Humana Insurance Company of Kentucky, Humana Insurance Company of New York, Humana Medical Plan of Michigan, Inc., Humana Insurance of Puerto Rico, Inc., Humana Medical Plan of Michigan, Inc., Humana Medical Plan of Pennsylvania, Inc., Humana Medical Plan of Utah, Inc., Humana Medical Plan, Inc., Humana Pharmacy Solutions, Inc., Humana Regional Health Plan, Inc., and Humana Wisconsin Health Organization Insurance Corporation.

18. Questcor survived the merger as a wholly owned indirect subsidiary of Mallinckrodt plc and continued to market Acthar thereafter, until changing its name to Mallinckrodt ARD, Inc. on July 27, 2015.

19. On January 26, 2019, Mallinckrodt ARD, Inc. converted to Mallinckrodt ARD LLC and it continues to market Acthar to this day.

20. **Mallinckrodt's Unnamed Agents and Co-Conspirators.** Mallinckrodt was joined in its scheme by several persons or groups of persons who served as agents, co-conspirators, aiders and abettors, or otherwise acted in concert in connection with Mallinckrodt's Acthar price schemes that have not been named as defendants in this matter but are nonetheless important to the claims herein.

21. The Competitor. Novartis marketed and sold Synacthen outside of the United States, and owned exclusive rights to sell Synacthen in the U.S. On information and belief, Novartis agreed to sell the Synacthen U.S. rights to Questcor with knowledge that Questcor did not intend to bring Synacthen to market to compete with Acthar.

22. The Consultant. BioSolutia Inc., now known as CareMetx, LLC ("BioSolutia") is a Maryland-based firm that provided health-care consulting services to Mallinckrodt, including through an individual consultant (the "BioSolutia Consultant") who was retained full time to work on Acthar, and who helped design and implement Mallinckrodt's schemes.

23. The Agents. Acthar is a "specialty pharmaceutical" and generally unavailable at most retail pharmacies. It is instead available primarily in specialty pharmacies, which focus on high-cost, high-complexity, and/or high-touch medication therapy for patients with complex disease states.

24. Because of this, in June 2007, Mallinckrodt agreed with Express Scripts Holding Company ("Express Scripts"), a Missouri-based pharmacy benefit management company, to provide integrated services critical to the scheme and to do so through certain of Express Scripts' subsidiaries. Each of these subsidiaries had separate

functions, but their coordinated purpose was to support and maintain Mallinckrodt's inflated Acthar prices, including by acting as Mallinckrodt's agent for purposes of pricing.

25. Priority Healthcare Distribution Inc., doing business as CuraScript SD ("CuraScript"), a Florida-based specialty pharmacy distributor, served as Mallinckrodt's exclusive distributor for Acthar. CuraScript was engaged by Mallinckrodt to deliver Acthar to the network of specialty pharmacies (including Humana Pharmacy), who then deliver the medicine to patients' homes. CuraScript may have been aided in this function by CuraScript, Inc., doing business as CuraScript SP Specialty Pharmacy, which itself operates specialty pharmacies in the United States. Both CuraScript and CuraScript SP Specialty Pharmacy were subsidiaries of Express Scripts.

26. United BioSource Corporation, formerly known as HealthBridge and now known as United BioSource LLC ("UBC"), a Pennsylvania-based company, provided pharmaceutical support services. During the most of the relevant time period, UBC was also an Express Scripts subsidiary, though Express Scripts completed its sale of UBC to a private equity firm in 2018. UBC designed and operationalized patient access centers that assist patients and prescribers with navigating prescription drug coverage and pharmacy options through patient access programs, including patient assistance programs, reimbursement, alternate funding and compliance services. UBC was engaged by Mallinckrodt to act as the administrator for the reimbursement of Acthar, interacting directly with patients and third-party payors by coordinating various patient-assistance programs, including the ASAP and PAP programs described further below.

27. Accredo Health Group, Inc., doing business as Liberty Pennsylvania, Medco Health Solutions, Liberty Texas, Gentiva, or Gentiva Health Services ("Accredo"), is also an Express Scripts subsidiary. Accredo is a specialty pharmacy services company that assists patients in obtaining medications, including by advocating for insurance coverage of the drug.

28. As applied to Acthar, UBC acted as the hub between these entities, designing and coordinating Acthar's sale, distribution, and reimbursement through its patient access programs. So, for example, when a doctor prescribes an initial or renewal course of Acthar to a patient, the prescription is sent to the "Acthar Hub" and a case manager is assigned to the patient through UBC or Accredo, which performs administrative services associated with obtaining insurance coverage of the drug from insurers such as Humana. Payment by the insurer or other payor is then made to CuraScript, which ships the medication to specialty pharmacies or directly to the patient. As set forth further below, CuraScript has no role in setting the price, which is functionally set by Mallinckrodt alone. CuraScript merely acts as Mallinckrodt's agent, collecting payment and shipping the medication.

29. The Charity. Chronic Disease Fund, Inc. ("CDF") is a Texas-based 501(c)(3) organization that now goes by the name Good Days From CDF or simply Good Days. Its putative mission is to provide co-pay assistance and other financial support to patients who meet the charity's application criteria.

30. The Prescribing Doctors. Mallinckrodt paid certain physicians (the "Prescribing Doctors") substantial sums to promote Acthar over other treatments. The Prescribing Doctors agreed with Mallinckrodt to promote and prescribe Acthar without disclosing to Humana or other payors their remuneration from Mallinckrodt. Not all of the Prescribing Doctors are known to Humana, and discovery is needed to identify them fully.

III. JURISDICTION AND VENUE

31. This court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action arises under the laws of the United States, including the Sherman Act, 15 U.S.C. § 1, *et seq.*, and 28 U.S.C. §1964(c), because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1962.

32. This Court has personal jurisdiction over Defendants pursuant to 15 U.S.C. § 53(b) because each Defendant has the requisite constitutional contacts with the United States of America.

33. This court has supplemental jurisdiction pursuant to 28 U.S.C. § 1367 over violations of state law, including state common law claims.

34. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c), and 18 U.S.C. § 1965.

35. A substantial part of the events giving rise to this action occurred in this judicial district. Questcor Pharmaceuticals Inc.—later renamed Mallinckrodt ARD Inc.—was until January 26, 2019 a California corporation. Prior to its 2014 acquisition by Mallinckrodt, Questcor was headquartered in Anaheim, California, in this judicial district. Several of the co-conspirator Prescribing Doctors are also located in the state of California, including one Prescribing Doctor whose offices are located in Los Angeles, California in this judicial district. Furthermore, Humana has more than 575,000 insureds in the state of California. Humana's operating subsidiary in California, Humana Health Plan of California, is located in Irvine, California in this judicial district.

IV. FACTUAL ALLEGATIONS

A. Humana

36. Congress established Medicare in 1965 to provide health insurance coverage for people aged sixty-five or older and for people with certain disabilities or afflictions. In 2003, Congress established a voluntary prescription drug benefit program for Medicare enrollees known as Medicare Part D. Under Medicare Part D, Medicare contracts with private entities, known as Part D Plan Sponsors, to administer prescription drug plans.

37. Under the Medicare statute, a Part D beneficiary may be required to make a partial payment for the cost of prescription drugs in the form of a co-payment, coinsurance, or deductible (collectively "co-pays"). The co-pays can be substantial for

expensive medications and vary throughout the year, depending on a beneficiary's total Part D covered expenses incurred that year up to that point.

38. Medicare co-pays exist to encourage physicians and beneficiaries to be efficient consumers of federally reimbursed health care products, while also encouraging those manufacturing such products to price them based on market forces such as consumer sensitivity and competition. Manufacturers paying the Medicare co-pays of those seeking to buy their drug circumvent this congressionally designed check on health care costs. As the United States Department of Health and Human Services, Office of the Inspector General has observed, drug manufacturers paying the Medicare Part D co-pays of patients taking their products "eliminat[e] a market safeguard against inflated prices." HHS-OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625 (Nov. 22, 2005).

39. Humana operates or administers Medicare Part D plans on behalf of the federal and state governments for millions of members. Humana also provides coverage for pharmaceuticals, including Acthar, through other plans, including medical insurance (Medicare Part B), Medicare Advantage (Medicare Part C), Medicaid, and commercial healthcare plans. Through its administration of these plans, Humana bears significant risk that the costs and utilization of healthcare services will rise. When Humana assumes these risks it relies in large part on the protections afforded by law against submissions of false or fraudulent claims to government healthcare providers.

40. Humana's agreements with its providers include a provision that requires the provider to certify its compliance with state and federal law, as well as rules promulgated by government entities such as the Centers for Medicare & Medicaid Services ("CMS"), a division of the Department of Health and Human Services that administers Medicare and Medicaid. These contractual provisions are essential for Humana to ensure that it receives prompt payments and reimbursements from CMS for valid claims, and to ensure that it does not pay invalid claims that might increase costs to both itself and Medicare.

B. Acthar

41. Acthar is an ACTH analogue used as an anti-inflammatory. Though its exact mechanism of operation is unclear, it is believed to stimulate the body's own steroidal hormones (such as cortisol and corticosterone), as well as to affect the body's steroid-independent immunomodulatory and anti-inflammatory pathways.

42. Acthar's active ingredient is extracted from pig pituitary glands. It was invented in 1948 by the pharmaceutical division of the Armour meatpacking and processing company. The original form of ACTH had a half-life of only 10 minutes, so Acthar was developed for clinical use by creating a repository gel tailored to a patient's individual needs. The gel must be refrigerated and is applied through either an intramuscular or a subcutaneous depot injection (i.e., an injection that deposits the drug in a localized mass, which is gradually absorbed by the body over an extended period).

43. Acthar's invention either was roughly contemporaneous with, or preceded, the development of certain corticosteroids, a class of steroids that can also be used to fight inflammation. Well-known examples of corticosteroids include hydrocortisone and prednisone. Acthar's invention also predated the discovery of ibuprofen and certain over-the-counter NSAIDs in pill form that are also used to combat inflammation.

44. The U.S. Food and Drug Administration ("FDA") first approved Acthar for marketing in the United States in 1952. This was before drugs were required to demonstrate "substantial evidence" of the efficacy for a marketed indication. Its original label lacked evidence from controlled clinical trials.

45. Acthar was approved to treat multiple sclerosis ("MS") in 1979. Today, it is approved for treatment of exacerbations of MS and also for indications of diseases and disorders that include rheumatic, collagen, dermatologic, and allergic states, as well as ophthalmic, respiratory, and edematous states. Specifically, these include idiopathic membranous nephropathy, the largest single cause of nephrotic syndrome, a kidney disorder; rheumatoid arthritis; dermatomyositis and polymyositis (inflammatory

diseases of the skin and muscles); symptoms of sarcoidosis (a disease that mainly affects the lungs and lymph glands); and inflammatory conditions of the eye.

46. However, there remains a lack of evidence to support the use of Acthar for most indications. The clinical evidence supporting the effectiveness of Acthar in treating some of these conditions consists of small (fewer than 25 participants) uncontrolled trials and case reports. For many of these conditions, Acthar is not considered the first-line treatment.

47. For most indications, there is also a lack of evidence to support Acthar's use over lower-cost synthetic corticosteroids, which can cost as little as $0.20 per pill (less than $20 for a typical course of treatment) as compared to the $39,000 per-vial cost of Acthar (or $117,000 for a three-vial treatment).

48. The only condition for which Acthar may be considered the most effective, "first-line" treatment is infantile spasms, an indication that the FDA approved in 2010.

49. Acthar was owned first by Armour Pharmaceutical Company, then by Rhone-Poulenc Rorer, and until 2001 by Aventis (now Sanofi). To that point, the drug was priced competitively with other anti-inflammatories. But since it was expensive to produce, difficult to apply, and (except for certain indications such as infantile spasms) not known to be more effective than simpler, cheaper, and more widely available drugs, Aventis considered discontinuing production. Questcor acquired worldwide rights to sell and manufacture Acthar from Aventis in July 2001. In view of what would come, the price was a pittance: $100,000, plus modest royalties.

C. Mallinckrodt's Monopoly Power with Acthar

1. Direct Evidence of Monopoly Power

50. Mallinckrodt has exercised monopoly power in the United States with Acthar. Ever since its acquisition of marketing rights in 2001, Mallinckrodt has charged supracompetitive prices for the drug.

51. Immediately after acquiring the rights to sell Acthar, Mallinckrodt's predecessor company Questcor increased the price from approximately $40 per vial to nearly $750 per vial.

52. By the end of 2006, Acthar accounted for 94 percent of Questcor's net sales. On August 27, 2007, Questcor increased the price of Acthar by more than 1,300% overnight, from $1,650 to $23,269 per vial. The decision to charge tens of thousands for a vial of Acthar was spearheaded by Questcor's chief executive, Don Bailey, who spent most of his career as an executive with a defense contractor, not in the pharmaceutical industry.

53. Questor has since raised the price of Acthar on multiple occasions since 2011 to $38,892 in 2018.

54. Acthar net sales increased from $218 million in 2011 to more than $1 billion in 2015.

55. Medicare spending on Acthar increased geometrically from 2011 to 2015, with total spending of nearly $2 billion and more than $600 million in 2016 alone. The following chart reveals how the number of Medicare Part D claims for Acthar has grown by more than 700% from 2011 to 2016:

Year	Claim Count	Total Spending
2011	1,471	$49,456,911
2012	3,387	$141,451,608
2013	6,752	$262,581,602
2014	9,611	$391,189,653
2015	11,209	$503,999,371
2016	12,867	$636,174,840
Total:	**45,297**	**$1,984,853,985**

2. Further Evidence of Monopoly Power

56. Several factors constitute further evidence of Mallinckrodt's monopoly power.

57. Lack of Competition. Mallinckrodt does not set the price of Acthar by reference to other drugs prescribed to treat the same indications that Acthar treats. Acthar is priced substantially higher than non-ACTH drugs used to treat the same indications. This suggests that there is no competitive constraint on Mallinckrodt's ability to set prices. Indeed, Acthar represents 100% of the market for ACTH drugs in the United States.

58. For example, Acthar costs nearly four times the amount of Sabril, the only other FDA-approved drug for the treatment of infantile spasms. But Sabril has a different molecular structure, works differently, and is prescribed for a smaller set of patients than Acthar. Acthar is also not considered a substitute for several earlier-line treatments for idiopathic membranous nephropathy. Most idiopathic membranous nephropathy patients are treated with low-cost drugs, and more severe cases might be treated with Rituxan, a drug that is still several factors less expensive than Acthar. And as with Sabril, these drugs operate differently than Acthar does.

59. One of the main reasons for the absence of competition or a lower-cost substitute is the unavailability of Synacthen. Mallinckrodt's conduct with respect to Synacthen is addressed further below.

60. High Barriers to Entry. Despite the lack of patent protection for Acthar, the U.S. ACTH market is still characterized by high barriers to entry. This includes FDA approval, which is required to market drugs to U.S. consumers. Drugs sold outside of the U.S. are therefore not viable substitutes.

61. Furthermore, developing a safe, effective, and reliable substitute would require substantial investments of resources and time, with no guarantee of success. One would have to source the active ingredient, develop a sustained-release depot-injection formulation, scale production, and conduct clinical trials, particularly because Acthar is derived from a biological and not a chemical process. Mallinckrodt's CEO has assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

3. Anticompetitive Conduct in the Acquisition of Synacthen

62. Synacthen is a synthetic ACTH drug with similar biological activities and pharmacological effects as Acthar. In Europe, Canada, and other parts of the world, doctors treat patients with Synacthen for the same conditions that are treated with Acthar in the U.S.

63. Questcor itself considered the drugs so similar that it submitted Synacthen information to support its application to the FDA to expand the label indications for Acthar. It also cited Synacthen studies in its Acthar marketing materials.

64. Before June 2013, Novartis marketed and sold Synacthen abroad. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly. Questcor therefore sought to acquire the rights to Synacthen as a defensive move to prevent competitors from acquiring it and developing it as a competitor to Acthar.

65. In late 2011, Novartis decided to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

66. Each of the three firms planned to develop and use Synacthen to compete directly with Acthar, and to price Synacthen well below Acthar. The three firms had the necessary expertise and financing, as well as sufficient business and regulatory plans, to develop Synacthen for the U.S. market.

67. The Synacthen asset package sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process. Because Synacthen had a long history of safe and effective use abroad, a buyer would not need to begin the research, development, testing, or manufacturing process from scratch. The asset package would therefore substantially lower the barriers to entry in the U.S. ACTH market.

68. The bidding process occurred in late 2012 and early 2013. Questcor signed a confidentiality agreement with Novartis and submitted an offer for Synacthen. Novartis negotiated with the three alternative bidders in parallel with Questcor, and each company had exchanged deal terms with Novartis and had submitted a formal offer. The offers by the three alternative bidders were comparable to each other in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. Synacthen sales. Unlike the three alternative bidders, however, Questcor had only inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis. It nevertheless submitted a bid several multiples higher than the other bidders.

69. On June 11, 2013, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"), that gave Questcor exclusive rights to develop, market, and sell Synacthen in the United States. Under the Agreements, Questcor is obligated to pay a minimum of $135 million to Novartis for Synacthen.

70. On information and belief, Novartis knew and understood that Questcor did not intend to develop Synacthen. This may be inferred from the fact that Questcor's bid for Synacthen was substantially higher than that of its competitors, even though Questcor had done far less, and was in a worse position, to bring Synacthen to market. In addition, Novartis was not naïve, and could be expected to understand that Questcor would have little interest in developing the only synthetic competitor to Acthar, its extraordinarily lucrative non-synthetic product.

71. Questcor claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the drugs' similarities, any therapeutic indication that Questcor might have pursued with Synacthen could have been pursued with Acthar.

72. Fourteen months after acquiring Synacthen, Mallinckrodt plc acquired Questcor for $5.6 billion, an amount almost entirely attributable to the value of Acthar.

73. Neither Questcor nor Mallinckrodt made more than superficial efforts to pursue commercialization of Synacthen, however. Instead Mallinckrodt chose to shelve the asset and thereby to protect Acthar monopoly pricing.

74. This conduct led the U.S. Federal Trade Commission ("FTC"), joined by the states of Alaska, Maryland, New York, Texas, and Washington, to bring an action against Mallinckrodt under the FTC Act, Section 2 of the Sherman Act, and state antitrust laws. On January 18, 2017, the FTC announced that Mallinckrodt had agreed to pay $100 million to settle the suit. The parties also filed and the court approved a stipulated court order requiring Questcor to grant a license to develop Synacthen to treat infantile spasms and nephrotic syndrome to a licensee approved by the FTC. On July 14, 2017, the FTC announced that it had approved a sublicense granting West Therapeutic Development, LLC certain rights to develop and market Synacthen in the United States.

4. Mallinckrodt's Sales of Acthar to Humana and its Members

75. Mallinckrodt has complete control over the price of Acthar and has on many occasions increased its price without negotiating with any of the purchasers or consumers of Acthar. Mallinckrodt is the sole entity with control over the wholesale acquisition cost (WAC) of Acthar that determines the price at which Acthar is sold throughout the pharmaceutical distribution chain. No other company has any influence over the price of Acthar in the marketplace.

76. Humana is obligated to and does pay the price of Acthar that Mallinckrodt sets. Mallinckrodt has purposefully sought to insulate itself from liability for the pricing of Acthar by engaging its co-conspirator Express Scripts as an intermediary in the sale of Acthar to all other purchasers. Express Scripts' CuraScript SD unit serves as the exclusive distributor of Acthar. But CuraScript SD has no independent authority to set the price of Acthar and bears no risk from Acthar sales. CuraScript bears no pricing risk for Acthar because it is guaranteed an adjustment in its acquisition costs if Mallinckrodt changes the price of Acthar. Furthermore, CuraScript is paid a fixed fee for each vial of

Acthar that is sold by Mallinckrodt (CuraScript SD does no marketing or selling of Acthar) so it does not incur any benefit or cost based on the price of Acthar. In 2009 that fixed fee was set at $230 per vial. CuraScript bears no risk of holding Acthar in inventory because Mallinckrodt has agreed to accept returns of any Acthar which goes unsold before its expiration date. With respect to sales of Acthar, CuraScript is completely controlled by Mallinckrodt and acts merely as its agent.

77. In addition to dictating its actions through contractual terms, Mallinckrodt confirmed that CuraScript SD was subject to its control by telling the SEC that if CuraScript SD were to fail to perform in the way that it wished, it could quickly and easily switch to a distributor who would provide "equivalent services." CuraScript SD had no choice but to comply with Mallinckrodt's directives because it was at risk of being terminated and replaced with a distributor that would. Furthermore, CuraScript SD's parent, Express Scripts, had many other lucrative consulting, administrative services, and specialty pharmacy sales arrangements with Mallinckrodt that would also be at risk if CuraScript SD did not perform at Mallinckrodt's command. CuraScript SD and its parent Express Scripts were not only complicit in, but actively took part in Mallinckrodt's scheme to further its monopoly in the ACTH drug market. As a co-conspirator and beneficiary of Mallinckrodt's scheme, there was no realistic possibility that CuraScript SD or its parent Express Scripts would ever bring suit against Mallinckrodt based on its anticompetitive actions.

78. Humana paid for more than $700 million worth of Acthar during the relevant period. Humana's Acthar purchases were made according to the wholesale cost that Mallinckrodt set and controlled. Humana purchased Acthar from Mallinckrodt's agent CuraScript SD and also from other specialty pharmacies that fulfilled prescriptions for its members.

79. In 2015, Humana's commercial insurance division directly contracted with Mallinckrodt for rebates based on its Acthar purchases made for members of Humana's commercial insurance plans. In January 2017, Humana's Medicare business entered

into a second rebate agreement with Mallinckrodt covering purchases made for members on Humana's Medicare plans. The claims and causes of action asserted in this complaint do not arise out of or relate to those agreements, and Humana is not asserting any claims or seeking any damages for breach of either of these agreements.

5. Scope of the Antitrust Allegations

80. Product. The relevant product is ACTH drugs.

81. Geographic Market. The relevant market is the entire United States.

82. Time. The relevant period is from 2011 through the present. Humana specifically alleges that the conduct and patterns of conduct alleged here occurred and continued to occur throughout this period.

D. Mallinckrodt's Kickback and Racketeering Schemes

83. Mallinckrodt designed and coordinated a multifaceted scheme (the "Acthar Enterprise") intended to charge and maintain inflated prices for Acthar, including through a conspiracy to defraud payors such as Humana. Built on Mallinckrodt's monopolistic practices, the scheme consisted of two subsidiary schemes: (1) illicit patient co-pay subsidies through sham charitable funds; and (2) kickbacks to the Prescribing Doctors.

1. Patient Co-Pay Subsidies Through Sham Charitable Funds

84. Not long after raising Acthar's price to over $23,000 per vial in 2007, Questcor knew that it might have priced itself out of the MS market because Acthar had many cheaper, effective competitors in that market. Questcor also understood that, for some insurance plans, the over-$23,000 price could lead to very high patient costs. Medicare Part D beneficiaries, in particular, could owe thousands of dollars in co-pays for one vial of Acthar.

85. Questcor realized that it could overcome doctor and patient cost concerns by subsidizing patient co-pay obligations, and thereby defrauding Medicare Part D payors like Humana. Questcor knew that it was illegal to subsidize Medicare co-pays directly, so it sought to accomplish the same result through a "co-pay assistance fund"

that it designed, created, and used as a money conduit to pay patient co-pay subsidies for Acthar (but no other drug).

86. The operation was spearheaded by the executives of Questcor and aided by the BioSolutia Consultant, who was retained full-time specifically for the purpose of assisting with Acthar reimbursement.

87. By the spring of 2010, Questcor had tried one foundation ("NORD") but was dissatisfied with what it considered to be the small scale of the operation, and looked instead for a foundation where it could fund co-pays on a much larger scale. This effort resulted in Questcor connecting with CDF to discuss starting a new fund for Questcor.

88. Though CDF already had a fund for MS patients, Questcor sought to establish an "MS Exacerbation Co-pay Fund" distinct from CDF's existing fund because Questcor did not want to make payments to a fund that might pay the co-pays of MS drugs other than Acthar.

89. After a presentation by CDF, Questcor moved its co-pay programs from NORD to CDF. Questcor and CDF established a new "MS Acute Exacerbation Fund" just for patients with government insurance, such as Medicare Part D, and just for the co-pays of Acthar but no other drugs. For patients with private insurance, Questcor had CDF open a separate Acthar "Private Fund" for Mallinckrodt to send private insurance patients to CDF to have Acthar co-pays paid. That fund also exclusively covered Acthar and Questcor financed that fund. Questcor's donation agreement falsely represented that the funds were generally for treatment of patients with acute exacerbations of MS, when in fact Questcor knew it was just for patients using Acthar. Questcor thereafter made co-pay assistance an important part of its sales and marketing program.

90. Questcor sent patients to CDF through Questcor's "reimbursement hub" for Acthar, called the Acthar Support and Access Program ("ASAP"), which was administered by UBC under Mallinckrodt's direction and control. Questcor and UBC controlled ASAP, which included a call center that received referrals for Acthar from

physician offices and patients. Questcor's sales force took steps to ensure that any Acthar prescriptions were routed through ASAP so that Questcor could track them. Patients sometimes had their co-pays paid for months or years through the fund.

91. In 2011, Questcor repeated this scheme in connection with a "Lupus Exacerbation" fund. Questcor financed the fund. It falsely stated that the fund was for "any medically appropriate therapy," when in fact Questcor intended to fund only Acthar and exclude other therapies. Questcor and UBC referred patients to the fund through ASAP and tracked the patients thereafter. And through 2014, the Lupus Exacerbation fund paid the co-pays of Acthar but no other drug, again often for months or years.

92. In 2012, Questcor repeated the scheme yet again for rheumatoid arthritis patients. It created an "RA Exacerbation Fund" at CDF, financed the fund, sent patients to the fund through ASAP with UBC's assistance, tracked the patients, and paid subsidies for sometimes months' or years' worth of refills of Acthar but no other drug.

93. That same year, Questcor became concerned that it would lose referrals to the fund for lack of co-pay assistance. Questcor therefore implemented an "automatic offering" of co-pay assistance to all patients with co-pays greater than $150, administered by UBC through the reimbursement hub. The ASAP program referred over 98 percent of the patients who received co-pay subsidies from the MS, Lupus, or RA Exacerbation funds at CDF.

94. During the same period that Questcor sent Acthar patients to CDF to receive Medicare co-pay subsidies, Questcor also retained NORD to operate a "Patient Assistance Program" ("PAP") that offered free Acthar to patients who met certain financial criteria and could not afford the drug's high price. ASAP also sent certain patients to NORD for that purpose. As with ASAP, the PAP program was administered by UBC under Mallinckrodt's direction and control. But Questcor intentionally did not send Acthar patients with Medicare or other insurance coverage for the drug to the NORD PAP. Instead, Questcor sent those patients to CDF, where they received co-pay

subsidies to cover their costs and triggered insurance reimbursement for Acthar. Questcor also required patients to appeal insurance coverage denials of Acthar before referring them to the PAP. In other words, whenever possible, Mallinckrodt sought to cause Medicare claims to be submitted for Acthar so that Mallinckrodt could get paid from a sale of the drug as opposed to giving it away for free through the NORD PAP.

95. Questcor marketed guaranteed co-pay assistance to physicians and patients as a way to neutralize concerns about the price and to induce sales and Medicare reimbursement. This began immediately after establishing the MS Acute Exacerbation Fund at CDF and continued throughout the relevant time period. For example, company training materials instructed the sales force: "DO NOT APOLOGIZE FOR THE PRICE." The training instead directed sales representatives to "[r]eview [the] co-pay coverage program" with prescribers who expressed concern about the drug's price.

96. Furthermore, after Questcor conducted research and discovered that price was an obstacle to more prescriptions, Questcor's internal remediation plan noted the importance of co-pay support.

97. Questcor's sales force continued to promote guaranteed Acthar co-pay subsidies through CDF in this manner, with the intent to induce Medicare Part D claims.

98. Questcor monitored its co-pay support programs by receiving detailed financial reports from CDF containing information about how many patients were enrolled in the fund, how much the fund had already paid out, and how much had been allocated to enrolled patients. The reports also stated the percentage of patients approved to receive co-pay subsidies, the average co-pay amount paid by the fund, the total number of resulting drug "dispenses" (broken out by new dispenses vs. refills), and the remaining fund balance. Because these funds paid Acthar co-pays only, all of these reported metrics were specific to Acthar. This gave Questcor the ability to monitor its fund balances and confirm the amount of future payments to CDF necessary to keep paying Acthar co-pay subsidies smoothly.

99. The funds worked as planned. After Questcor established the co-pay conduit at CDF, Questcor achieved significant growth in Acthar MS sales and corporate revenue. For example, Acthar MS sales nearly quadrupled between the third quarter of 2010 (when Questcor established the MS "acute exacerbation" fund) and the third quarter of 2013.

100. Questcor also intensified its dramatic price increases. On January 3, 2011 Questcor raised Acthar's price to over $24,430 per vial. Under six months later, it raised the price again to over $25,600 per vial. In December 2011, it raised the price to over $27,300 per vial. In May 2012, it raised the price to over $28,680 per vial. In June 2013, it raised the price to over $30,100 per vial. In January 2014, it raised the price to over $31,600 per vial. In December 2014 it raised the price to over $32,200 per vial.

101. The Company knowingly and willfully violated the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), by paying illegal Acthar co-pay subsidies as described above to induce prescriptions and sales of Acthar reimbursed by Medicare, and knowingly and willfully violated the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and its prohibition on submitting, or causing to be submitted, false claims to federal health care programs, including Medicare. The Company's knowledge and willfulness is evidenced by internal training materials that instructed its employees on these laws and their relevant prohibitions; corporate policies reflecting the Company's knowledge of its illegality; trade publications and articles circulated among the key executives and consultants warning against the practice; and longstanding and repeated warnings about the practice from the Office of the Inspector General of the United States Department of Health and Human Services.

102. On information and belief, Mallinckrodt continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 and continues to do so until today.[2]

[2] Mallinckrodt, "Acthar Reimbursement and Copayment Support," https://www.actharishcp.com/reimbursement-and-copay (last visited August 4, 2019).

2. Physician Kickbacks

103. The second part of the Acthar Enterprise consisted of kickbacks to the Prescribing Doctors in exchange for increased prescriptions of Acthar.

104. Mallinckrodt's co-pay subsidies were one way to prop up demand and receive payment from third-party payors such as Humana. Another was Mallinckrodt's aggressive push to move away from prescriptions for infantile spasms and towards conditions affecting elderly patients, and therefore to increase reimbursement by Medicare and third-party payors like Humana. Mallinckrodt has heavily marketed Acthar to neurologists (for MS), to nephrologists (for idiopathic membranous nephropathy and nephrotic syndrome), to rheumatologists (for a variety of conditions including rheumatoid arthritis), to pulmonologists (for sarcoidosis), and to ophthalmologists (for severe allergic or inflammatory eye conditions).

105. In 2014 the president of the autoimmune and rare-disease business selling Acthar made a presentation to investors detailing a strategy to expand Acthar's sales to patients in rheumatology, pulmonology, ophthalmology, dermatology, and kidney disease. In the several decades prior, Acthar had not been prescribed in large quantities for these conditions despite having been FDA approved for such treatments. Although there were no new medical studies suggesting Acthar was needed to treat any of these conditions, the president pledged to "expand significantly" Acthar's sales force in the fields of rheumatology and pulmonology in the upcoming year. That sales effort was wildly successful at expanding the market for Acthar beyond infantile spasms. Now fewer than 10% of Acthar's sales come from prescriptions for infantile spasms, and more than 98% of Humana's expenditures for Acthar were made for insureds over the age of 18.

106. A 2018 study published in JAMA Network Open concluded that "[a]ggressive sales tactics and payments from [Mallinckrodt] may influence prescribing behavior for [Acthar]." Indeed their "findings suggest that financial conflicts of interest may be driving use of corticotropin in the Medicare program." The study examined

Medicare data about the providers who submitted more than ten claims for Acthar. It noted that "[a]mong the 50 prescribers (21.3%) who received more than $10 000 in payments during the year [2015], corticotropin expenditures per prescriber (mean [SD], $1 304 884 [$1 022 937]) were more than double that of the 45 prescribers (19.2%) who received $25 or less (mean [SD], $594 976 [$256 357])." The study's invariable regression analysis further showed that "Medicare spending on [Acthar] increased by 7.9% (approximately $53 000) for every $10 000 increase in payments to prescribers," or a return of investment of approximately 5:1. The study further noted that 207 of 235 frequent corticotropin prescribers (88%) who submitted more than 10 claims received a corticotropin-related payment from Mallinckrodt. By contrast, a recent study found that among all specialists, only 35% receive payments from the pharmaceutical industry.

107. From 2013 to 2016, Mallinckrodt paid doctors nearly $27.5 million in Acthar-related payments. A handful of doctors received unusually large sums of money: during the same period, Mallinckrodt paid more than $6.5 million to only 288 prescribers for consulting, promotional speaking, and other services related to Acthar.

108. Many of the top prescribers to Humana's members have been paid substantial fees by Mallinckrodt. These include the following:

Prescribing Doctor	Specialty	Amount Paid By Mallinckrodt to the Prescribing Doctor (Payment Dates)	Amount Humana Paid for Acthar Prescriptions by These Doctors
1	Int. Med./Sarcoidosis	$116,000 (2013-2015)	$10,672,325
2	Rheumatology	$22,762 (2013-2015)	$4,841,709
3	Rheumatology	$273,937 (2013-2016)	$3,459,480
4	Neurology	$142,978 (2013)	$2,723,683
5	Rheumatology	$267,701 (2013-2016)	$1,928,838
6	Rheumatology	$370,970 (2013-2016)	$778,060
7	Psychiatry/Neurology	$345,913 (2013-2016)	$739,894
8	Rheumatology	$224,713 (2013-2016)	$612,561
9	Neurology	$332,393 (2013-2016)	$379,250

The goal of Mallinckrodt's scheme was to increase its sales of Acthar at the expense of those who paid for it—primarily health insurers such as Humana. Mallinckrodt required the assistance and complicity of the Prescribing Doctors to achieve its ends. It knew

that in order to increase the prescription rates of Acthar, the Prescribing Doctors would need to prescribe Acthar in situations in which it was not called for and in lieu of considerably more cost-effective medications.

3. False Representations and Certifications

109. In order to effectuate its scheme, Mallinckrodt either made or caused to be made three kinds of false representations and certifications directly to Humana.

110. *First*, Mallinckrodt directly misrepresented to Humana that it was complying with state and federal law, including laws related bribery, kickbacks, and false claims.

111. When a pharmacy dispenses drugs to a Humana Part D member, the pharmacy submits a claim to Humana, which in turn submits an electronic record of the claim, called a Prescription Drug Event ("PDE"), to CMS. After dispensing the drug, the pharmacy receives reimbursement from Humana for the portion of the drug cost not paid by the Part D member at the point of sale.

112. PDE claims data are necessary for CMS to administer the Part D program and to reimburse Part D Plan Sponsors such as Humana. Generating and submitting PDE data is a condition of payment for CMS' provision of Medicare funds to Part D Plan sponsors. *See* 42 C.F.R. § 423.322.

113. Part D Plan Sponsors must comply with "[f]ederal laws and regulations designed to prevent fraud, waste, and abuse, including, but not limited to, applicable provisions of Federal criminal law, the False Claims Act (31 U.S.C. § 3729, *et seq.*), and the anti-kickback statute (§ 1127B(b)) of the Act)." 42 C.F.R. § 423.505(h)(l). Any "downstream" or "related" entities that Part D Plans subcontract with (including pharmacies dispensing medication and manufacturers selling medication) must also comply with these, and any other, contractual obligations of the Part D Plan and with all applicable federal laws, regulations, and CMS instructions. *See* 42 C.F.R. § 423.505(i)(3).

114. CMS regulations require Part D Plan Sponsors and related "downstream" entities that generate and submit PDE claims data to certify that such data is true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the health care products or services reflected therein. *Id.* § 423.505(k). Congress has determined that any Medicare claim "that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g).

115. Mallinckrodt and its captive agent CuraScript made such certifications and therefore directly misrepresented to Humana that they were complying with federal law.

116. *Second*, when providers, including the Prescribing Doctors, prescribe pharmaceutical treatment, they must generally obtain prior authorization from insurers such as Humana. By going through the prior authorization process, the Prescribing Doctors represent to Humana that the prescription medication is medically necessary, up-to-date, and non-duplicative. They are further representing that they are not violating state or federal law applicable to the provision of their services.

117. Mallinckrodt, CDF, and the Prescribing Doctors knew that offering or accepting money or other consideration in exchange for prescriptions was a violation of the law and CMS policies and procedures. Mallinckrodt, CDF, and the Prescribing Doctors knew that their enterprise was a violation of these rules because it involved a payment in exchange for an increased rate of prescriptions.

118. Through its unlawful payments to the Prescribing Doctors and its payments to patients through the CDF funds, Mallinckrodt caused false certifications and representations to be made to Humana during the prior authorization process.

119. *Third*, Humana members are required to pay what they owe for drug coverage under Medicare Part D and other kinds of plans, and they are advised in their evidence of coverage documents that they must pay their share of the cost when they obtain prescription drugs. Through its illegal scheme to pay patient co-pays through phony charitable funds at CDF, Mallinckrodt caused Humana members to

unintentionally misrepresent that they had paid their contractual share of prescription drug coverage.

4. Use of the Mails and Wires

120. Throughout the relevant period, Mallinckrodt, CDF, and the Prescribing Doctors used thousands of mail and interstate wire communications to create and manage their scheme, which involved nationwide distribution of Acthar through the Prescribing Doctors and CuraScript at the direction of Mallinckrodt. Mallinckrodt communicated with the Prescribing Doctors through the mails and wires, caused thousands of reimbursement requests to be submitted by the Prescribing Doctors over the wires or by mail, and made illegal kickback payments to the Prescribing Doctors over the wires or by mail.

E. Mallinckrodt's Fraudulent Concealment of the Illegal Scheme

121. Mallinckrodt actively concealed the existence of its illegal scheme and the acts underlying it through false or misleading statements to Humana and to the public. Mallinckrodt falsely maintained that it would develop and seek FDA approval of Synacthen when in reality it purposefully failed to put the effort and resources into obtaining a broad FDA approval of Synacthen as an alternative to Acthar. Mallinckrodt also failed to disclose to Humana its arrangements with CDF that created specialized funds that were illegally to reimburse co-payments for Acthar, despite its certifications to Humana that it was following federal law and CMS rules that prohibited such co-payment subsidies for Medicare patients. Finally, Mallinckrodt also failed to disclose its kickback payments to doctors that violated federal law and CMS rules despite its certifications to Humana that it was abiding by such laws and CMS rules.

122. Due to Mallinckrodt's fraudulent concealment, Humana could not have discovered and remained unaware of the foregoing conduct until the Federal Trade Commission and the United States Department of Justice brought these acts and practices to light through investigations, legal actions, and/or settlements.

F. Damages

123. As a result of Mallinckrodt's multipronged scheme to inflate Acthar's price and utilization, Humana incurred significant losses. A substantial portion of Humana's business is evaluating, underwriting, and managing risks involved in insuring healthcare costs. As a commercial insurer, Humana bears significant risk of utilization of unnecessary, ineffective, or uneconomical medical care. The same is true for Humana's Medicare plans.

124. For Humana's Medicare business, Humana bears the risk of rising prescription drug prices and utilization in part through Part D "risk corridors" and Medicare Advantage capitation payments. Both of these Medicare provisions shift risk from the federal government to Humana to pay for some or all of the increased costs of prescription drugs for the Medicare members it covers. As such, Humana benefits financially when costs and utilization of prescription drugs are lower than expected and conversely it is harmed when costs and utilization of prescription drugs are higher than expected. In addition, for the portion of costs covered by the government under these programs, Humana bears a risk of non-payment if claims are found to be false or fraudulent by the government.

125. The risk of fraudulent claims is one that is shared by Humana and the government sponsors of healthcare plans that Humana administers. Therefore the claims of the government and the claims of Humana against Mallinckrodt are substantially the same.

126. Mallinckrodt's scheme was designed to cause and did cause Humana and others to pay for Acthar prescriptions that they would otherwise not have reimbursed and to pay more for those prescriptions than they otherwise would have paid. Humana was among the group of health insurers who were the targets of Mallinckrodt's scheme. Mallinckrodt knew that nearly all of its sales of Acthar in the United States would be sold to patients who carried prescription drug insurance that would bear the majority of

Acthar's cost. Humana's insurance plans bore the majority of Acthar's costs for its members and was directly injured as a result of Mallinckrodt's illegal conduct.

127. But for Mallinckrodt's scheme to perpetuate its ACTH monopoly, illegally subsidize Humana's members' co-pays, and pay kickbacks to Prescribing Doctors, Humana would have paid for fewer Acthar prescriptions and it would have paid less for those prescriptions that it otherwise would have covered. Specifically, but for Mallinckrodt's monopolistic conduct, including its acquisition of Synacthen, Humana would have benefitted from increased competition in the market for ACTH drugs and would have either paid lower prices for Acthar or it would have steered its members to lower priced Synacthen. Similarly, but for Mallinckrodt's kickbacks, Mallinckrodt and the Prescribing Doctors would not have defrauded Humana by falsely certifying their compliance with federal and state law through submissions for reimbursements for Acthar prescriptions. Finally, but for Mallinckrodt's kickback scheme and illegal co-pay assistance through CDF, prescription rates for Acthar would have been lower, and Humana members would have received different care from their physicians that was more effective, less harmful, or more cost effective than doses of Acthar.

128. As a consequence of Mallinckrodt's conduct, Humana paid over $700 million for Acthar prescriptions. In the absence of such conduct, Humana would have paid a small fraction of that amount. Humana has also incurred administrative, investigative, legal, and other costs as a result of Mallinckrodt's conduct.

Count I

Violation of the Sherman Antitrust Act, 15 U.S.C. § 2

129. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

130. Mallinckrodt has, and at all relevant times had, monopoly power in the market for the sale of ACTH drugs in the United States.

131. By intervening in the bidding process for Synacthen and purchasing the exclusive license to market Synacthen in the United States, Mallinckrodt eliminated the

potential competitive threat posed by an independently owned Synacthen license. Mallinckrodt's conduct was reasonably capable of contributing significantly to the preservation of Mallinckrodt's monopoly power and monopoly pricing of Acthar in the United States.

132. The effect of Mallinckrodt's actions to maintain its monopoly was to stabilize or raise the price of Acthar to a higher level than it would have commanded in the absence of the monopolistic conduct.

133. Humana suffered injuries when it paid those higher prices.

134. Defendants' acts and practices constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

Count II

Violation of the Sherman Antitrust Act, 15 U.S.C. § 1

135. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

136. Mallinckrodt entered into an exclusive agreement with Novartis to license the right to market Synacthen in the United States.

137. That agreement restrained trade in the market for the sale of ACTH drugs in the United States.

138. The effect of that agreement was to maintain or raise the price of Acthar to a higher level than it would have commanded in the absence of the agreement.

139. Humana suffered injuries when it paid those higher prices.

140. The agreement between Mallinckrodt and Novartis constitutes an anticompetitive agreement in restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

Count III

Violation of State Antitrust Laws

141. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

142. The aforementioned practices by Defendants that violate Sections 1 and 2 of the Sherman Act were and are also violations of the following states' antitrust laws:

a. Ala. Code § 6-5-60, *et seq.* (Alabama);

b. Ariz. Rev. Stat. Ann. § 44-1401, *et seq.* (Arizona);

c. Cal. Bus. & Prof. Code § 16750, *et seq.* (California);

d. Conn. Gen. Stat. Ann. § 35-24, *et seq.* (Connecticut);

e. D.C. Code Ann. § 28-4501, *et seq.* (D.C.);

f. Fla. Stat. Ann. § 501.201, *et seq.* (Florida);

g. Haw. Rev. Stat. Ann. § 480-1, *et seq.* (Hawaii);

h. 740 Ill. Comp. Stat. Ann. 10/1, *et seq.* (Illinois);

i. Iowa Code Ann. § 553.1, *et seq.* (Iowa);

j. Kan. Stat. Ann. § 50-101, *et seq.* (Kansas);

k. Me. Rev. Stat. tit. 10, § 1101, *et seq.* (Maine);

l. Mich. Comp. Laws Ann. § 445.771, *et seq.* (Michigan);

m. Minn. Stat. Ann. § 325D.49, *et seq.* (Minnesota);

n. Miss. Code. Ann. § 75-21-1, *et seq.* (Mississippi);

o. Neb. Rev. Stat. Ann. § 59-801, *et seq.* (Nebraska);

p. Nev. Rev. Stat. Ann. § 598A.010, *et seq.* (Nevada);

q. N.M. Stat. Ann. § 57-1-1, *et seq.* (New Mexico);

r. N.Y. Gen. Bus. Law § 340, *et seq.* (New York);

s. N.C. Gen. Stat. § 75-1, *et seq.* (North Carolina);

t. Or. Rev. Stat. Ann. § 646.705, *et seq.* (Oregon);

u. S.D. Codified Laws § 37-1-3.1, *et seq.* (South Dakota);

v. Tenn. Code Ann. § 47-25-101, *et seq.* (Tennessee);

w. Utah Code Ann. § 76-10-3101, *et seq.* (Utah);

x. Vt. Stat. Ann. tit. 9, § 2451, *et seq.* (Vermont);

y. Wis. Stat. Ann. § 133.01, *et seq.* (Wisconsin).

Count IV

Violation of the RICO Act, 18 U.S.C. § 1962(c)

143. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

144. Mallinckrodt is a "person" within the meaning of 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

145. The Acthar Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Mallinckrodt, Express Scripts and its relevant subsidiaries (including CuraScript), CDF, and the Prescribing Doctors—including their corporate parents, siblings, subsidiaries, employees, and agents. The Acthar Enterprise was an ongoing organization that functioned as a continuing unit. The Acthar Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Mallinckrodt, Express Scripts, CuraScript, CDF, and the Prescribing Doctors are each "persons" distinct from the Acthar Enterprise.

146. Mallinckrodt established the Acthar Enterprise to fraudulently increase its sales of Acthar. Mallinckrodt subsidized co-pays through CDF, and paid the Prescribing Doctors, in exchange for an increased rate of prescriptions of Acthar in lieu of less expensive alternative treatment. Mallinckrodt, CDF, and the Prescribing Doctors knew that their scheme violated federal and state laws.

147. Such payments also violated state commercial bribery statutes which prohibit offering anything of value to a fiduciary for the purpose of altering the fiduciary's conduct towards those to whom he owes fiduciary duties. Doctors, like the Prescribing Doctors, owe fiduciary duties to their patients to offer medical advice and counseling based on the best interest of the patient, not what is in their own pecuniary interest.

148. False representations of compliance with federal and state laws were made to Humana for payment over the wires or by mail. These false representations were

made directly to Humana and were a condition of reimbursement by Humana for all Acthar claims submitted by the Prescribing Doctors. The illegal payments were sent over the wires or by mail to the Prescribing Doctors and to CDF.

149. The Acthar Enterprise engaged in and affected interstate commerce because, among other things, it marketed, sold, purchased, or provided Acthar to thousands of individuals throughout the United States.

150. Mallinckrodt has asserted control over the Acthar Enterprise by issuing payments to doctors who prescribed Acthar as treatment for conditions for which more affordable alternative treatments were readily available. Mallinckrodt asserted control over the enterprise by utilizing one exclusive distributor, CuraScript, and setting the price of Acthar paid by Humana.

151. Mallinckrodt has asserted control over the Acthar Enterprise by designing, organizing, and funding the phony charitable funds at CDF used for Acthar co-pays.

152. Mallinckrodt has conducted and participated in the affairs of the Acthar Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), 1952 (use of interstate facilities to conduct unlawful activity), and state bribery statutes.

153. The effect of Mallinckrodt's racketeering activity was to induce sales of Acthar that otherwise would not have been made in the absence of the illegal conduct and to maintain or raise the price of Acthar to a higher level than it would have commanded in the absence of the illegal conduct.

154. Humana suffered injuries when it reimbursed those prescriptions for Acthar that otherwise would not have been made and/or paid the higher prices that resulted from the illegal conduct.

155. Humana's injuries were directly and proximately caused by Mallinckrodt's racketeering activities as described above.

156. By virtue of these violations of 18 U.S.C. § 1962(c), Mallinckrodt is jointly and severally liable to Humana for three times the damages Humana has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Count V

Conspiracy to Violate the RICO Act, 18 U.S.C. § 1962(d)

157. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

158. Title 18 U.S.C. § 1962(d) provides that it "shall be unlawful for any person to conspire to violate any of the provisions of subsection (a), (b) or (c) of this section."

159. Mallinckrodt has violated 18 U.S.C. § 1962(d) by conspiring with the Prescribing Doctors, CuraScript, and CDF to violate 18 U.S.C. §1962(c). The object of this conspiracy has been and is to conduct or participate in, directly or indirectly, the conduct of the affairs of the Acthar Enterprise described previously through a pattern of racketeering activity.

160. Mallinckrodt and its co-conspirators have engaged in numerous overt and predicate fraudulent racketeering acts in furtherance of the conspiracy, including material misrepresentations and omissions designed to defraud Humana of money.

161. The nature of the above-described Mallinckrodt's co-conspirators' acts, material misrepresentations, and omissions in furtherance of the conspiracy gives rise to an inference that they not only agreed to the objective of an 18 U.S.C. § 1962(d) violation of RICO by conspiring to violate 18 U.S.C. § 1962(c), but they were aware that their ongoing fraudulent and extortionate acts have been and are part of an overall pattern of racketeering activity.

162. As a direct and proximate result of Mallinckrodt's overt acts and predicate acts in furtherance of violating 18 U.S.C. § 1962(d) by conspiring to violate 18 U.S.C. § 1962(c), Humana has been injured in its business and property as set forth more fully above.

163. Mallinckrodt and its co-conspirators have sought to and have engaged in the commission of overt acts, including the following unlawful racketeering predicate acts:

a. Multiple instances of mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1342;

b. Multiple instances of mail fraud in violation of 18 U.S.C. §§ 1341 and 1346;

c. Multiple instances of wire fraud in violation of 18 U.S.C. §§ 1343 and 1346;

d. Multiple instances of unlawful activity in violation of 18 U.S.C. §1952;

e. Multiple instances of bribery in violation of state statutes, including but not limited to Cal. Penal Code § 641.3, 720 Ill. Comp. Stat. 5/29A-1, Tex. Penal Code § 32.43, N.J. Stat. § 2C:21-10, and N.Y. Penal Law § 180.00.

164. The purpose and effect of the conspiracy was to induce sales of Acthar that otherwise would not have been made in the absence of the illegal conduct and to maintain or raise the price of Acthar to a higher level than it would have commanded in the absence of the illegal conduct.

165. Humana suffered injuries when it reimbursed those prescriptions for Acthar that otherwise would not have been made and/or paid the higher prices that resulted from the illegal, conspiratorial conduct.

166. Humana's injuries were directly and proximately caused by Mallinckrodt's racketeering activities as described above.

167. By virtue of these violations of 18 U.S.C. § 1962(d), Mallinckrodt is jointly and severally liable to Humana for three times the damages Humana has sustained, plus the cost of this suit, including reasonable attorneys' fees.

Count VI

State Unfair Competition Law Claims

168. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

169. Mallinckrodt and its co-conspirators have engaged in fraudulent and deceptive business practices that violate the state unfair competition laws of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, the District of Columbia, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

170. Mallinckrodt and its co-conspirators have engaged in unfair competition under the states' laws by unlawfully making and accepting remuneration in exchange for the sale of Acthar to Humana and its members in consumer transactions. This conduct violated the federal AKS and equivalent state statutes and caused the certifications of compliance with law provided by the Prescribing Doctors to Humana to be fraudulent.

171. Plaintiff Humana was directly and proximately injured by Mallinckrodt and its co-conspirators' conduct and would not have paid what it did for Acthar had Mallinckrodt fully disclosed its schemes.

172. Mallinckrodt engaged in wrongful conduct while at the same time obtaining under false pretenses a significant sum of money from plaintiff Humana. Humana suffered injury in fact and actual damages including lost money and property as a result of Mallinckrodt's violations of:

a. Ala. Code § 8-19-1, *et seq.* (Alabama);

b. A.S. § 45.50.471(a), *et seq.* (Alaska);

c. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.* (Arizona);

d. Ark. Code Ann. § 4-88-101, *et seq.* (Arkansas);

e. Cal. Bus. & Prof. Code § 17200, *et seq.* (California);

f. Colo. Rev. Stat. § 6-1-101, *et seq.* (Colorado);

g. Conn. Gen. Stat. § 42-110a, *et seq.* (Connecticut);

h. D.C. Code § 28-3901, *et seq.* (D.C.);

i. Del. Code Ann. tit. 6, § 2511, *et seq.* (Delaware);

j. Fla. Stat. § 501.201, *et seq.* (Florida);

k. Ga. Code Ann. § 10-1-390, et seq. (Georgia);

l. Haw. Rev. Stat. §§ 480-2, et seq. (Hawaii);

m. Idaho Code Ann. § 48-601, *et seq.* (Idaho);

n. 815 Ill. Comp. Stat. 505/1, *et seq.* (Illinois);

o. Ind. Code § 24-5-0.5-1, *et seq.* (Indiana);

p. Iowa Code § 714.16, *et seq.* (Iowa);

q. Kan. Stat. Ann. § 50-623, *et seq.* (Kansas);

r. Ky. Rev. Stat. Ann. § 367.110, *et seq.* (Kentucky);

s. La. Rev. Stat. Ann. § 51:1401, *et seq.* (Louisiana);

t. Me. Rev. Stat. Ann. tit. 5, § 205A, *et seq.* (Maine);

u. Md. Code Ann., Com. Law § 13-101, *et seq.* (Maryland);

v. Mass. Gen. Laws Ann. ch. 93A, § 1, *et seq.* (Massachusetts);

w. Mich. Comp. Laws § 445.901, *et seq.* (Michigan);

x. Minn. Stat. § 325F.68, *et seq.* (Minnesota);

y. Miss. Code Ann. § 75-24-1, *et seq.* (Mississippi);

z. Mo. Rev. Stat. § 407.010, *et seq.* (Missouri);

aa. Mont. Code Ann. § 30-14-101, *et seq.* (Montana);

bb. Neb. Rev. Stat. § 59-1601, *et seq.* (Nebraska);

cc. Nev. Rev. Stat. § 598.0903, *et seq.* (Nevada);

dd. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.* (New Hampshire);

ee. N.J. Stat. Ann. § 56:8-1, *et seq.* (New Jersey);

ff. N.M. Stat. § 57-12-1, *et seq.* (New Mexico);

gg. N.Y. Gen. Bus. Law § 349, *et seq.* (New York);

hh. N.C. Gen. Stat. § 75-1.1, *et seq.* (North Carolina);

ii. N.D. Cent. Code § 51-15-01, *et seq.* (North Dakota);

jj. Ohio Rev. Code Ann. § 1345.01, *et seq.* (Ohio);

kk. Okla. Stat. tit. 15, § 751, *et seq.* (Oklahoma);

ll. O.R.S. 646.607, et seq. (Oregon);

mm. Pa. Stat. Ann. § 201-1, et seq. (Pennsylvania);

nn. R.I. Gen. Laws § 6-13.1-1, et seq. (Rhode Island);

oo. S.C. Code Ann. § 39-5-10, et seq. (South Carolina);

pp. S.D. Codified Laws § 37-24-1, et seq. (South Dakota);

qq. Tenn. Code Ann. § 47-18-101, *et seq.* (Tennessee);

rr. Tex. Bus. & Com. Code Ann. § 17.41, *et seq.* (Texas);

ss. Utah Code Ann. § 13-11-1, *et seq.* (Utah);

tt. Vt. Stat. Ann. tit. 9, § 2451, *et seq.* (Vermont);

uu. Va. Code Ann. § 59.1-196, *et seq.* (Virginia);

vv. Wash. Rev. Code § 19.86.010, *et seq.* (Washington);

ww. W. Va. Code § 46A-6-101, *et seq.* (West Virginia);

xx. Wis. Stat. § 100.18, *et seq.* (Wisconsin);

yy. Wyo. Stat. Ann. § 40-12-101, *et seq.* (Wyoming).

173. Pursuant to these states' laws, Humana seeks judgment in its favor and against Mallinckrodt requiring Mallinckrodt to pay restitution of wrongful profits, revenues, and benefits received as a result of the Acthar schemes.

Count VII

State Consumer Fraud and Deceptive Trade Practice Law Claims

174. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

175. Mallinckrodt and its co-conspirators have engaged in fraudulent and deceptive business practices that violate the state consumer fraud, consumer protection , and/or deceptive trade practices laws of Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Indiana, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, North Carolina, South Carolina, Tennessee, and Wisconsin, and in particular the following laws:

a. Ariz. Rev. Stat. Ann. § 44-1521, *et seq.* (Arizona);

b. Ark. Code Ann. § 4-88-101, *et seq.* (Arkansas);

c. Cal. Bus. & Prof. Code § 17200, *et seq.* (California);

d. Colo. Rev. Stat. § 6-1-101, *et seq.* (Colorado);

e. Conn. Gen. Stat. § 42-110a, *et seq.* (Connecticut);

f. Fla. Stat. § 501.201, *et seq.* (Florida);

g. Ga. Code Ann. § 10-1-390, *et seq.* (Georgia);

h. 815 Ill. Comp. Stat. 505/1, *et seq.* (Illinois);

i. Ind. Code § 24-5-0.5-1, *et seq.* (Indiana);

j. La. Rev. Stat. Ann. § 51:1401, *et seq.* (Louisiana);

k. Md. Code Ann., Com. Law § 13-101, *et seq.* (Maryland);

l. Mass. Gen. Laws Ann. ch. 93A, § 1, *et seq.* (Massachusetts);

m. Mich. Comp. Laws § 445.901, *et seq.* (Michigan);

n. Minn. Stat. § 325F.68, *et seq.* (Minnesota);

o. Neb. Rev. Stat. § 59-1601, *et seq.* (Nebraska);

p. Nev. Rev. Stat. § 41.600, *et seq.* (Nevada);

q. N.H. Rev. Stat. Ann. § 358-A:1, *et seq.* (New Hampshire);

r. N.C. Gen. Stat. § 75-1.1, *et seq.* (North Carolina);

s. S.C. Code Ann. § 39-5-10, *et seq.* (South Carolina);

t. Tenn. Code Ann. § 47-18-101, *et seq.* (Tennessee);

u. Wis. Stat. § 100.18, *et seq.* (Wisconsin).

176. Humana is a person or consumer entitled to protection under the foregoing state laws.

177. Mallinckrodt directly misrepresented to Humana that it was complying with federal and state laws, including laws against bribery, kickbacks, and false claims to the government. In addition, through its payments to doctors, Mallinckrodt induced the Prescribing Doctors to falsely certify to Humana through the prior authorization process that they had not received any illegal kickbacks from manufacturers.

178. Mallinckrodt intended payors such as Humana to rely on these certifications. The intention may be inferred by the very nature of the representation, whose sole purpose is to procure payment for Acthar.

179. These representations and certifications were made in an effort by Mallinckrodt to sell Acthar to the consuming public, and were addressed to the market generally by having Acthar paid for at inflated prices by Medicare, Medicaid, and third-party payors such as Humana. The ultimate consequence of this conduct is a significant injury to the consuming public by, among other things, imposing additional costs on the taxpaying public for Medicare, raising the cost of insurance, and obstructing the availability of Acthar and its synthetic substitute to consumers.

180. Humana relied on these misrepresentations to its detriment, which were material to its decision to pay for Acthar treatments.

181. Humana was directly and proximately injured by Mallinckrodt and its co-conspirators' conduct, suffered an injury in fact, and suffered actual, ascertainable damages. Humana would not have paid for Acthar, or would have paid only a small fraction of the amount it actually did pay, had Mallinckrodt refrained from engineering the false representations or otherwise disclosed its schemes.

182. Mallinckrodt's conduct offends established public policy and the public interest, and is immoral, unethical, oppressive, unscrupulous, and substantially injurious to consumers.

Count VIII

State Insurance Fraud Claims

183. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

184. Mallinckrodt and its co-conspirators have committed insurance fraud in violation of the laws of California, Illinois, Kentucky, Pennsylvania, New Jersey, North Carolina, and Tennessee, and in particular the following laws:

a. Cal. Ins. Code §1871, *et seq.* (California);

b. 720 ILCS 5/17-10.5; 740 ILCS 92/1, *et seq.*(Illinois);

c. Ky. Rev. Stat. § 304.47-011, *et seq.* (Kentucky);

d. 18 Pa. Cons. Stat. Ann. § 4117 (Pennsylvania);

e. N.J. Stat. § 17:33A, *et seq.* (New Jersey);

f. N.C. Gen. Stat. §§ 58-2-160, *et seq.* (North Carolina);

g. Tenn. Code Ann. §§ 56-53-101 (Tennessee).

185. Mallinckrodt knowingly presented or caused to be presented to Humana statements in support of claims for insurance benefits for Acthar that it knew contained false and/or misleading information. Mallinckrodt knew and intended that by engaging in its schemes to pay kickbacks to doctors and illegally subsidize co-payments through phony charitable funds that misleading and/or false information would be submitted to Humana and other Medicare payors in connection with insurance claims.

186. The statements of the co-conspirator doctors who prescribed Acthar and the pharmacies who filled Acthar prescriptions to Humana were false because they certified compliance with federal and state laws and regulations that were not, in fact, complied with. Among the laws which the doctors and pharmacies were not in compliance with were the anti-kickback statutes.

187. The compliance certifications were material to Humana's decision to reimburse claims for Acthar that Mallinckrodt caused to be submitted. Had the

certification of compliance with federal and state laws and regulations been withheld or corrected by the doctors or pharmacies, Humana would not to have paid these claims.

188. Humana's injuries were directly and proximately caused by the false or misleading statements that Mallinckrodt made to it, or caused to be submitted to it, as described above.

Count IX

Tortious Interference with Contractual Relations

189. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

190. Humana had valid and enforceable written contracts with each of its members who were prescribed Acthar during the relevant period. These agreements specify that members will pay their share of the costs for prescription drugs. The purpose of this co-payment obligation is to provide an incentive to members to exercise patient responsibility for health care costs, and so to help control health care and health insurance costs on a larger scale.

191. Mallinckrodt was aware that patients were in contractual relationships with payors, including Humana, providing for such requirements, because those requirements are ubiquitous and, in the case of Medicare, are dictated by statutes and regulations.

192. Mallinckrodt intended to and did induce Humana members to breach their obligations by subsidizing their co-pays.

193. Humana was harmed by these breaches because it reimbursed claims for Acthar that otherwise would not have been made.

194. Mallinckrodt has intentionally interfered with the contracts between Humana and its members.

195. Humana seeks judgment in its favor and against Mallinckrodt, requiring Mallinckrodt to pay monetary and punitive damages for the conduct described herein.

Count X

Unjust Enrichment

196. Humana incorporates by reference each of the above paragraphs of this Complaint as though fully stated herein.

197. As the intended and expected result of their conscious wrongdoing as set forth in this Complaint, Mallinckrodt has profited and benefited from payments Humana made for Acthar as a result of its schemes.

198. The circumstances of Mallinckrodt's receipt of monies based on the conduct set forth in this Complaint are such that, in equity and good conscience, Mallinckrodt should not retain such monies, the amount of which is to be determined at trial.

199. Humana is entitled in equity to seek restitution of Mallinckrodt's wrongful profits, revenues and benefits received as a result of its schemes.

200. Humana states this claim to the extent that it is deemed not to have an adequate legal remedy.

V. PRAYER FOR RELIEF

201. Based on the foregoing, Humana requests that the Court enter an order that:

a. Enters judgment in favor of Humana and against Defendants;

b. Awards Humana its actual damages in an amount to be determined at trial;

c. Awards Humana punitive damages;

d. Awards Humana treble damages under 15 U.S.C. § 15(a), 18 U.S.C. § 1964(c), or any other provision of law, including state law, that permits doubling or trebling of damages;

e. Awards Humana its attorneys' fees and litigation costs under 15 U.S.C. § 15(a), 18 U.S.C. § 1964(c), or any other provision of law, including state law, that permits recovery of such costs and fees;

f. Awards Humana pre-and post-judgment interest; and

g. Provides any other relief that the Court deems proper.

VI. JURY DEMAND

202. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury on all issues so triable.

Dated: August 8, 2019

By: Jeremy D. Matz

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